UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	**CASE NO. _____**
This Document Relates To:	**FOR INCLUSION IN: MDL NO. 1:13-MD-2419-FDS**
Frank Dale Jenkins	**JURY DEMAND**

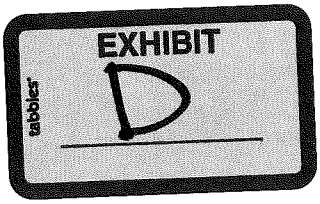
COMPLAINT

1. Plaintiffs, Frank Dale Jenkins and Betty Jenkins, bring this Complaint for Damages against Defendants Ameridose, LLC, Medical Sales Management Inc., GDC Properties Management, LLC, Barry Cadden, Lisa Cadden, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro and Glenn A. Chin (hereinafter collectively referred to as "Defendants"), for the injuries arising from the injection of a contaminated caudal epidural steroid administered to Frank Jenkins to ease his chronic back pain. In support Plaintiffs allege and state as follows:

PARTIES

2. Plaintiffs are both domiciliaries and residents of Henderson County, Kentucky. Plaintiffs have been married for fifty-four (54) years.

3. Defendant Ameridose, LLC (hereinafter "Ameridose"), is a Massachusetts limited liability corporation whose principal place of business is located at 201-205 Flanders Road, Westborough, Massachusetts, 01581. Ameridose is a sister company to New England Compounding Company (hereinafter "NECC"), which also manufactures and sells drug products, and shares common ownership with NECC. Ameridose is managed and controlled by



Gregory Conigliaro and Barry Cadden. Ameridose's registered agent for service is Gregory Conigliaro, 205 Flanders Road, Westborough, MA.

4. Defendant Medical Sales Management, Inc. (hereinafter "MSM"), is a Massachusetts corporation with its principal place of business located at 697 Waverly Street, Framingham, Massachusetts, 01702. Douglas Conigliaro is the President and a Director of MSM, Barry Cadden is the Treasurer and a Director of MSM, and Gregory Conigliaro serves as the Secretary and a Director of MSM. MSM's registered agent for service is Gregory Conigliaro.

5. Defendants, Ameridose, MSM, and GDC share common ownership with NECC. NECC has not been named as a Defendant in the instant action in light of pending bankruptcy proceedings.

6. Defendant GDC Properties Management, LLC (hereinafter "GDC") is a Massachusetts limited liability company with its principal place of business located at 701 Waverly Street, Framingham, Massachusetts, 01702. Upon information and belief, GDC leased premises at 701 Waverly Street, Framingham, Massachusetts to NECC and MSM.

7. Defendant Barry J. Cadden was an owner of NECC and served as the President, Head Pharmacist, and Director of Pharmacy at NECC. His job responsibilities at NECC included, but were not limited to, overseeing day to day operations. Upon information and belief, Barry Cadden also engaged in compounding medications during his tenure as Head Pharmacist at NECC. Barry Cadden was a founder and Manager of Ameridose, where he was also responsible for overseeing day-to-day operations. Mr. Cadden also served as the Treasurer and a Director of MSM. Barry Cadden may be served at his residence located at 13 Manchester Drive, Wrentham, MA.

8. Defendant Lisa Conigliaro Cadden served as a board member, Director, and pharmacist at NECC. Upon information and belief, during her tenure at NECC Mrs. Cadden was involved in the day-to-day operations of NECC and engaged in the practice of compounding drugs. Lisa Cadden may be served at her residence located at 13 Manchester Drive, Wrentham, MA.

9. Defendant Gregory Conigliaro is the principal owner, Treasurer, Secretary, Vice President, and a Director of NECC. Gregory Conigliaro' s duties and job responsibilities included, but were not limited to, providing financial advice and overseeing day-to-day operations. As a result, Gregory Conigliaro was present at NECC facilities on a regular basis. In addition, Gregory Conigliaro is the founder and Manager of Ameridose and also serves as the Secretary and a Director of MSM. Gregory Conigliaro may be served at his residence located at 1 Mountain View Drive, Framingham, Massachusetts.

10. Defendant Douglas Conigliaro is the President and a Director of MSM. Upon information and belief, Douglas Conigliaro is involved in the day to day operations of NECC, Ameridose, and MSM. Douglas Conigliaro can be served at his residence located at 15 Hale Drive, Dedham, Massachusetts.

11. Defendant Carla Conigliaro is a Director of NECC. She may be served at her residence located at 2110 Fawsett Road, Winter Park, Florida.

12. Defendant Glenn A. Chin was an employee and leader at NECC who was present during the course of both state and federal investigations of NECC's premises. Glenn Chin may be served at his residence located at 173 Mechanic Street, Canton, Massachusetts.

13. Defendants engaged in the manufacture, distribution, compounding, promotion, testing, marketing, and/or sale of contaminated injectable steroid medications in the State of Indiana.

JURISDICTION

14. This Court has jurisdiction pursuant to 28 U.S.C. §1332 as full diversity of citizenship exists among the parties. Furthermore, the amount in controversy is substantially in excess of seventy-five thousand dollars ($75,000), exclusive of interest and costs. Alternatively, this Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because as described herein each claim asserted herein is related to a case under title 11.

15. Venue is proper in accordance with Case Management Order No. 6 (Dkt. No. 209), previously entered in *In re: New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL No. 1:13-md-2419 FDS (hereinafter "the MDL"). Plaintiffs submit that this complaint meets the qualifications set forth for direct filing into the District of Massachusetts for inclusion in MDL 2419. Absent direct filing, Plaintiffs state that venue would be proper in the Southern District of Indiana as a substantial part of the events or omissions giving rise to the claim occurred within said district.

FACTUAL BACKGROUND

16. New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), is a corporation that manufactures, sells, fabricates, and supplies injectable steroids. NECC is a Massachusetts Corporation with its principal place of business located at 697 Waverly Street, Framingham, Massachusetts. Specifically, NECC operates as a compounding pharmacy compounding, distributing, and/or selling drugs to purchasers throughout the United States, including purchasers within the State of Indiana.

17. Upon information and belief, NECC is a privately held company that is owned and controlled by Defendants Barry Cadden, Gregory Conigliaro, Douglas Congiliaro, Carla Conigliaro, and Lisa Cadden.

18. At all times relevant hereto Defendants, Ameridose, GDC, and MSM, were affiliates of NECC and shared common ownership.

19. NECC produced more than 17,000 tainted steroid injections, made of preservative-free methylprednisolone acetate (known as "MPA steroid injections"). These NECC MPA steroid injections were tainted with at least two types of funguses, Aspergillus and Exserohilum.

20. According to the Center for Disease Control ("CDC"), the injections were distributed to medical providers in twenty-three (23) states, including Indiana. Indiana healthcare facilities received lots of the tainted MPA steroid injections in Evansville, Fort Wayne, Elkhart, South Bend, Terre Haute, and Columbus.

21. On September 26, 2012, a recall of the suspect lots of the MPA steroid injections was instituted and investigations were launched. NECC subsequently surrendered its Massachusetts license and suspended operation. All NECC products have since been recalled.

22. According to the CDC, there have been 750 reported cases of fungal infections linked to the NECC MPF steroid injections and sixty-four (64) deaths nationwide.

23. Medication compounding involves the practice of taking commercially available products and modifying them to meet the needs of an individual patient pursuant to a prescription from a licensed provider. Common examples of compounding include changing a medication from a solid to a liquid, removing an ingredient a patient may be allergic to, or adding a flavoring to medication

24. NECC was licensed in Massachusetts and only authorized to prepare and sell compounded medications to specific individuals for whom they had received an individual prescription request from a health care provider.

25. During a joint-investigation ("the investigation") by the Massachusetts Department of Health ("MDH") and the Food and Drug Administration ("FDA"), investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk.

26. NECC distributed large batches of compounded sterile products directly to facilities for general use rather than requiring a prescription for an individual patient, as required by law. Manufacturing and distributing sterile products in bulk was not allowed under the terms of its state pharmacy licenses.

27. NECC distributed two of the recalled lots of MPF steroid injections prior to receiving the results of sterility testing, as required by law.

28. In performing final sterilization of the MPF steroid injections, NECC did not follow proper standards for autoclaving, sterilization through a high pressure stream, pursuant to United States Pharmacopeia Standard 797 (USP 797) and NECC's own Standard Operation Procedures. In fact, the investigation found that NECC's own records indicated a systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

29. The investigation uncovered the unsafe conditions of NECC's facilities. The investigation found that visible black particulate matter was seen in several recalled sealed vials of the contaminated MFA steroid injections. Additionally, the "tacky" mats used to trap

potential contaminants were visibly soiled with assorted debris and a leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth.

30. NECC filed for Chapter 11 bankruptcy on or about December 21, 2012. NECC's bankruptcy remains pending before the U.S. Bankruptcy Court for the District of Massachusetts, Case No. 12-19882-HJB. As a result, NECC has not been named as a Defendant in this complaint.

Plaintiff's Injuries

30. Mr. Jenkins is an eighty-one (81) year old, white male residing in Henderson County, Kentucky with his wife Betty Jenkins.

31. Mr. Jenkins has suffered from chronic lower back pain for years caused by prominent lumbar spondylosis with lumbar facet arthritis, degenerative disc disease, and intervertebral disc displacement for which he sought medical treatment.

32. Mr. Jenkins underwent conservative care with oral medication but still his symptoms persisted.

33. On August 1, 2012 at St. Mary's Medical Center in Evansville, Indiana, Dr. William A. Ante treated Mr. Jenkin's back pain with a caudal epidural steroid injection. Dr. Ante injected 1.5mL of methylprednisolone by spinal needle.

34. On September 19, 2012, Mr. Jenkins returned to St. Mary's Medical Center with persistent lower back pain, despite having some relief from the August 1st treatment. Dr. Ante again treated Mr. Jenkins's back pain with a caudal epidural steroid injection consisting of 1.5mL of methylprednisolone.

35. St. Mary's Medical Center assumed the name Surgicare Outpatient Surgical Center in 2006[1] and operates as St. Mary's Surgicare. Surgicare Outpatient Surgical Center is also the assumed name of Ambulatory Care Center, LLC.

36. The CDC lists Ambulatory Care Center, LLC as one of the healthcare facilities that received lots of MPA steroid injections recalled from NECC on September 26, 2012.[2]

37. Mr. Jenkins received two letters from St. Mary's Surgicare informing Mr. Jenkins of the contamination of NECC MPA steroid injections and warning him of the possible symptoms associated with fungal meningitis.

38. Mr. Jenkins developed some of the listed symptoms and reported to the emergency room at Methodist Hospital on October 9, 2012.

39. While at Methodist Hospital, Mr. Jenkins was tested and subsequently diagnosed with a fungal meningitis infection.

40. As a result of Mr. Jenkins' exposure to a contaminated NECC MPA injection, Mr. Jenkins has endured significant mental and physical pain and suffering, has sustained permanent injury, including, but not limited to neuropathy, has undergone medical treatments and will likely need to undergo further medical treatments, has suffered financial loss including, but not limited to, obligations for medical services and expense and/or loss of income, and other damages.

COUNT I
(Strict Liability - Defective Design or Manufacture)

41. Plaintiffs incorporate the allegations set forth in Paragraphs 1 through 40.

42. The Indiana Products Liability Act provides for negligence and strict product liability actions for defective products in Indiana.[3]

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[1] Indiana Secretary of State Business Services Division.
[2] http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html.
[3] IND. CODE. § 34-20-1-1, *et seq*.

43. "[A] person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property is subject to liability for physical harm caused by that product . . . if (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition; and if (2) the seller is engaged in the business of selling such a product; and, (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable."[4]

44. A product is unreasonably dangerous if "the product exposes the user or consumer to a risk of physical harm to an extent beyond that contemplated by the ordinary consumer who purchasers the product with the ordinary knowledge about the product's characteristics common to the community of consumers."[5]

45. Defendants researched, designed, developed, manufactured, labeled, marketed, promoted, supplied, distributed and sold the subject MPA steroid injections which were defective and unreasonably dangerous to consumers, including the Plaintiff.

46. Defendants expected the MPA steroid injections, to reach and it did reach consumers, including Plaintiffs, without substantial change in the condition in which it was manufactured and sold by Defendants.

47. Plaintiff, Frank Jenkins, was administered a caudal MPA steroid injection in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

48. The MPA steroid injections administered to Mr. Jenkins failed to perform safely when used as instructed or in a reasonably foreseeable manner.

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[4] IND. CODE § 34-20-2-1.
[5] IND. CODE § 34-20-2-1.

49. When placed into the stream of commerce, the MPA steroid injections were defective in their design or formulation and were unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with its design or formulation. When placed into the stream of commerce, Defendants MPA steroid injections were defective in design or formulation in that they posed a greater likelihood of injury and danger than ordinary consumers or their physicians could reasonably foresee or anticipate.

50. Alternatively, when placed into the stream of commerce, the MPA steroid injections were defective in design and were unreasonably dangerous in that their label failed to warn physicians and patients that the MPA steroid injections were contaminated and failed to warn physicians and patients of the dangers associated with their use, including but not limited to, the risk of developing fungal meningitis.

51. Although Defendants, knew or should have known, of the defective nature of the MPA steroid injections, they continued to design, manufacture, label, market and sell MPA steroid injections so as to maximize sales and profits at the expense of the public health and safety. Defendants acted with knowing, conscious and deliberate disregard of the foreseeable harm caused by their MPA steroid injections.

52. As a direct and proximate cause of the defective design of the MPA steroid injections, Plaintiff Frank Jenkins suffered severe and permanent physical and emotional injuries, including but not limited to fungal meningitis and subsequent neuropathy.

53. As a further direct and proximate result of Plaintiff Frank Jenkins' use of Defendants MPA steroid injections, the Plaintiff Frank Jenkins has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

COUNT II
(Strict Liability - Failure to Warn)

54. Plaintiffs incorporate the allegations set forth in Paragraphs 1 through 53.

55. The Indiana Products Liability Act imposes strict liability on a manufacturer when the manufacturer puts a product into the stream of commerce without reasonable, adequate warnings thereby leaving it in a condition unreasonably dangerous to any user, if such warnings could have been given in the excise of reasonable diligence fails to give reasonable warnings of danger about the product.[6]

56. The MPA steroid injection, ultimately use to treat Mr. Jenkins, was not accompanied with an adequate warning to alert physicians or consumers of the dangerous risks associated with the product, including, without limitation, the contaminated nature of the product and the failures of Defendants to follow and comply with reasonable standards for the manufacture and sale of the MPA steroid injections.

57. The Defendants, being fully aware of the unsanitary and illegal conditions of NECC, had an ongoing duty to warn physicians and patients of the dangers associated with the MPA steroid injections.

58. Defendants have engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting MPA steroid injections, and through that conduct have knowingly and intentionally placed MPA steroid injections into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff Mr. Jenkins.

59. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendants and administered to the Plaintiff Frank Jenkins. The defective

[6] IND. CODE. ANN. § 34-20-2-2; *Marshall v. Clark Equipment Co.*, 680 N.E.2d 1102, 1105 (Ind. Ct. App. 1997).

condition of Defendants' MPA steroid injections was due in part to the fact that they were not accompanied by proper warnings to alert physicians and consumers of the contamination or to warn of the possible side effect of developing fungal meningitis as a result of their use.

60. This defect caused serious injury to Plaintiff Frank Jenkins, who used the contaminated MPA steroid injections in an intended and foreseeable manner.

61. At all times herein mentioned, Defendants had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

62. Defendants so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

63. Defendants negligently and recklessly failed to warn of the nature and scope of the risks associated with use of their contaminated MPA steroid injections.

64. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendants knew or should have known that contaminated MPA steroid injections caused serious injuries, it failed to exercise reasonable care to warn of the dangerous side effects, including but not limited to, developing fungal meningitis from MPA steroid injection use, even though these risks were known or reasonably scientifically knowable at the time of distribution. Defendants willfully and deliberately failed to avoid the consequences associated with its failure to warn, and in doing so, Defendants acted with a conscious disregard for the safety of consumer, including Plaintiff, Frank Jenkins.

65. Had Defendants properly disclosed the risks associated with their MPA steroid injections, Plaintiff Frank Jenkins would have avoided the risk of developing meningitis by not using the MPA steroid injections.

66. As a direct and proximate result of Defendants' failure to warn Mr. Jenkins, or his physicians, of the dangers associated with the use of their contaminated MPA steroid injections, Mr. Jenkins suffered serious and permanent injuries, including, but not limited to, extreme pain and recurrent infections.

67. In accordance with IND. CODE 34-20-2-1, 34-20-2-2, and 34-20-2-3, Defendants are strictly liable to Plaintiffs for all damages they have suffered as a result of the defective MPA steroid injections.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory, treble, and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT III
(Negligence)

68. Plaintiffs incorporate the allegations set forth in Paragraphs 1 through 67.

69. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiffs herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of their MPA steroid injections.

70. Defendants breached their duty of reasonable care to Plaintiffs in that they negligently promoted, marketed, distributed, and labeled the subject product.

71. Plaintiffs' injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

(a) In their design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of the subject product;

(b) In their failure to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiffs herein, of the MPA steroid injections' dangerous and defective characteristics;

(c) In failing to warn and/or adequately and sufficiently warn of the contamination of the aforementioned products and the risks associated with their use including but not limited to meningitis, spinal injury, brain damage, and death;

(d) In failing to meet all appropriate and required conditions, standards, regulations, and requirements for the safe and reliable dispensing of said products;

(e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

(f) In failing to adequately and sufficiently warn, after discovering or after a time in which they should have discovered, physicians and consumers, of the contamination and associated risks, including but not limited to, meningitis, spinal injury, brain damage, and death;

(g) In failing to properly instruct physicians, medical providers, the public health community, and medical facilities to test for contamination and

quality assurance before administering Defendants MPA steroid injections to patients;

(h) In failing to adequately and properly test MPA steroid injections for contamination before and after placing them on the market;

(i) In failing to correct mold and bacteria contamination, document and known to Defendants, within NECC;

(j) In failing to properly maintain and inspect sterilization equipment;

(k) In failing to follow or adhere to standard sterilization operating procedures;

(l) In failing to conduct proper and adequate testing and surveillance to determine and assess the safety of subject products;

(m) In failing to maintain a clean and sterile working environment for the compounding of MPA steroid injections and failing to properly protect against cross-contamination;

(n) In failing to adhere to and maintain proper standard operating procedures, record-keeping and work conditions; and

(o) In failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks of associated with the use of MPA steroid injections; and

(p) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risks of serious personal injury associated with the use of Defendants contaminated MPA steroid injections.

72. Gregory Conigliaro, as principal owner of NECC, and manager of related entities Ameridose and MSM, played a substantial role in the manufacture and sale of the products at issue and knew or should have known of the potential for contamination present in the compounding facility. However, Gregory Conigliaro failed to take any action to ensure products were compounded in a safe and sterile environment, were free from contamination, and/or that products were safe for their reasonably intended and foreseeable uses. He had the opportunity and ability to ensure that the MPA steroid injections compounded by NECC were adequately tested and inspected prior to sale but failed to inspect and/or test such products for contamination.

73. Defendant, Barry Cadden, as an owner, the President, and Directory of Pharmacy NECC, and manager of related entities Ameridose and MSM, played a substantial role in the manufacture and sale of the contaminated MPA steroid injections. Barry Cadden knew or should have known of the potential for contamination present in the compounding facility. However, Mr. Cadden failed to take any action to ensure products were compounded in a safe and sterile environment, were free from contamination, and/or that products were safe for their reasonably intended and foreseeable uses. He had the opportunity and ability to ensure that the MPA steroid injections compounded by NECC were adequately tested and inspected prior to sale but failed to inspect and/or test such products for contamination.

74. Lisa Conigliaro Cadden, as a member of the board of directors for NECC, and as a practicing licensed pharmacist, played a substantial role in the manufacture and sale of the contaminated MPA steroid injections. Lisa Cadden knew or should have known of the potential for contamination present in the compounding facility. However, Mrs. Cadden failed to take any action to ensure products were compounded in a safe and sterile environment, were free from

contamination, and/or that products were safe for their reasonably intended and foreseeable uses. She had the opportunity and ability to ensure that the MPA steroid injections compounded by NECC were adequately tested and inspected prior to sale but failed to inspect and/or test such products for contamination.

75. As an individual heavily involved in the day-to-day operations of NECC and a licensed physician, Defendant, Douglas Conigliaro, played a substantial role in the manufacture and sale of the contaminated MPA steroid injections. Douglas Conigliaro knew or should have known of the potential for contamination present in the compounding facility. However, Mr. Conigliaro failed to take any action to ensure products were compounded in a safe and sterile environment, were free from contamination, and/or that products were safe for their reasonably intended and foreseeable uses. He had the opportunity and ability to ensure that the MPA steroid injections compounded by NECC were adequately tested and inspected prior to sale but failed to inspect and/or test such products for contamination.

76. As an owner and officer of NECC, Carla Conigliaro, had a substantial responsibility to oversee and ensure that the products being manufactured and sold by NECC were safe for their intended and/or foreseeable use. Carla Conigliaro knew or should have known of the potential for contamination present in the compounding facility. However, Carla Conigliaro failed to take any action to ensure products were compounded in a safe and sterile environment, were free from contamination, and/or that products were safe for their reasonably intended and foreseeable uses. She had the opportunity and ability to ensure that the MPA steroid injections compounded by NECC were adequately tested and inspected prior to sale but failed to inspect and/or test such products for contamination.

77. Glenn Chin, as a pharmacist, employee, and leader at NECC played a substantial role in the manufacture and sale of the contaminated MPA steroid injections. Mr. Chin knew or should have known of the potential for contamination present in the compounding facility. However, Glenn Chin failed to take any action to ensure products were compounded in a safe and sterile environment, were free from contamination, and/or that products were safe for their reasonably intended and foreseeable uses. He had the opportunity and ability to ensure that the MPA steroid injections compounded by NECC were adequately tested and inspected prior to sale but failed to inspect and/or test such products for contamination.

78. Defendant GDC as lessor of the premises leased to NECC had a high degree of control over NECC premises and had a duty to ensure that said premises were properly maintained and sanitary in accordance with all local and state laws and regulations. GDC knew or should have known of the potential for contamination present in the NECC compounding facility.

79. Defendants owed a duty as a manufacturer and seller of the MPA steroid injections such that they would be in reasonably safe condition when delivered to physicians and ultimately to patients.

80. Defendants were negligent in designing, manufacturing, and selling contaminated MPA steroid injections by failing to undertake requisite sterilization procedures and also by knowingly producing the MPA steroid injections in an unsafe environment.

81. This negligence was the direct and legal cause of Plaintiffs' injuries.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory, treble, and punitive damages, together with interest, costs herein

incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

COUNT IV
(Breach of Warranty)

82. Plaintiffs incorporate the allegations set forth in Paragraphs 1 through 81.

83. Mr. Jenkins is a "person" within the meaning of Ind. Code 26-1-1-201(30).

84. The MPA steroid injections sold by NECC are "goods" within the meaning of Ind. Code 26-1-2-105(1).

85. At the time of the acts complained of herein, NECC was a "seller" of the MPA steroid injections within the meaning of Ind. Code 26-1-2-103(1)(d), and a "merchant" within the meaning of Ind. Code 26-1-2-104(1) with respect to MPA steroid injections.

86. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and sold contaminated MPA steroid injections, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff, Frank Jenkins, that the subject product was of merchantable quality and safe and fit for the use for which it was intended.

87. Defendants were aware that consumers, including Plaintiff, would use the MPA steroid injections for pain management treatment.

88. Plaintiff, Frank Jenkins, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

89. Mr. Jenkins used the subject product for its intended purpose.

90. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after he used it.

91. Contrary to the implied warranty for the subject product, Defendants' MPA steroid injections were not of merchantable quality, and were neither safe nor fit for their intended use and purpose, as alleged herein.

92. The condition of the MPA steroid injections violated the implied warranty of merchantability provided by Indiana law.[7]

93. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff, Frank Jenkins, suffered severe physical and emotional injuries. Plaintiffs have endured pain and suffering, have suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory, treble, and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiffs also demands that the issues herein contained be tried by a jury.

COUNT V
(Loss of Consortium)

94. Plaintiffs incorporate the allegations set forth in Paragraphs 1 through 93.

95. Mr. Frank Jenkins has been married to Mrs. Betty Jenkins for fifty-four (54) years.

96. For the past year and what will likely be many more, Mr. Jenkins has suffered immense physical and psychological pain as a result of his fungal meningitis infection. His mobility, independence, and quality of life have been severely negatively impacted by his injuries.

[7] IND. CODE ANN. § 26-1-2-314.

97. Mrs. Betty Jenkins has also suffered physically and mentally as a result of Mr. Jenkins' fungal meningitis infection.

98. Betty Jenkins is therefore entitled to recover from Defendants for her loss of consortium.

COUNT VI
(Alter Ego – Joint Venture)

99. Plaintiffs incorporate the allegations set forth in Paragraphs1 through 98.

100. Defendants, Ameridose, and MSM at all times material hereto are and were organized and operated as the alter ego of NECC, for the benefit and advantage of Defendants, and NECC exercised dominion and control over Ameridose, and MSM.

101. Defendants NECC, Ameridose, and MSM have intermingled their business activities and affairs with one another to the extent that each Defendant is an alter ego of the others.

102. Defendants, NECC, Ameridose, and MSM operated as a joint venture and/or in concert with one another at all times material hereto.

103. Defendants, NECC, Ameridose, and MSM, are the same in substance and are alter egos of one another, acting together to deceive and cause harm and/or prejudice to creditors of the corporations, including but not limited to, Plaintiffs.

104. Defendants, NECC, Ameridose, and MSM may be, or are virtually or actually insolvent. Due to the scope of harm caused by these Defendants, the officers and directors of NECC, Ameridose, and MSM, including Barry Cadden, Lisa Cadden, Gregory Conigliaro, Douglas Conigliaro, and Carla Congilario, owe a fiduciary duty to Plaintiffs.

105. The officers and directors of NECC, Ameridose, and MSM, participated in, were aware of, and acquiesced to the deceptive and manipulative practices set forth in this Complaint,

and are jointly and severally liable for the acts, failures to act, and/or omissions of NECC, Ameridose, and MSM.

COUNT VII
(Punitive Damages)

106. Plaintiffs incorporate the allegations set forth in Paragraphs 1 through 105.

107. The Indiana Supreme Court has found that punitive damages are appropriate when "a reasonable trier of fact could find by clear and convincing evidence that the defendant acted with malice, fraud, gross negligence or oppressiveness which was not the result of a mistake of fact or law, honest error of judgment, overzealousness, mere negligence or other human failing."[8]

108. Defendants sold the MPA steroid injections, despite the visibly unsafe and unsanitary conditions of NECC's facilities, including the black particulate matter, soiled tacky mats, and standing water.

109. Defendants sold their MPA steroid injections with full knowledge of the systemic failure to keep products in the autoclave for the requisite amount of time.

110. Because Defendants knowingly and intentionally failed to comply with state and federal law with respect to the operations of NECC, presumably to increase profits from selling the MPA steroid injections, Defendants acted with gross negligence.

111. As a result of the Defendants grossly negligent acts, punitive damages should be awarded to the Plaintiffs under Indiana law.

[8] *Budget Car Sales v. Stott*, 662 N.E. 2d 638, 639 (Ind. 1996).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering, for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interests and costs as provided by law;
2. Restitution and disgorment of profits;
3. Reasonable attorneys' fees;
4. The costs of all proceedings;
5. All ascertainable economic damages;
6. An award of punitive damages;
7. Such other and further relief this Court deems just and proper.

JURY TRIAL DEMAND

Plaintiffs demand a jury trial on all issues so triable.

Dated: November 06, 2013.

Respectfully submitted,

/s/ Christopher L. Coffin
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